Michael A. McCrea, PhD, ABPP-CN
Professor

Department of Neurosurgery
Brain Injury Research Program

The Role of Rehabilitation in Concussion Management
Research Opportunity Instructions for Athletes and Parents

Dear Athletes and Parents:

We are delighted that administration, coaches, and athletic training staff at your school have elected to participate in *The Role of Rehabilitation in Concussion Management.* We hope that you will individually choose to participate in this project. To do so, permission from the athlete and written consent from a parent is required. We are sending this packet to provide you with information on the project, along with a request that you complete a few easy steps to participate in the research project.

Attached to this cover sheet, you will find the following:

1. A one page document describing the research study
2. An informed consent form for the research project entitled "The Role of Rehabilitation in Concussion Management: A Randomized Controlled Trial"

Instructions:

1. Athletes, please take this packet home to your parents the same day you receive it.
2. Athletes and parents, please review the Informed Consent Form.
3. Parents, if you agree to allow your child to participate, please print your name, sign, and date on the Parent/Subject lines. One parent signature is adequate.
4. Athletes, if you also agree to participate, please print your name, sign and date the Assent of Minor lines.

AFTER COMPLETING THESE STEPS, WE ASK THAT THE ATHLETE RETURN THIS FORM TO EITHER THEIR HEAD COACH OR ATHLETIC TRAINER AT THEIR SCHOOL AS SOON AS POSSIBLE.

Please contact Dr. Michael McCrea, Principal Investigator for this research study, if you have any questions regarding this packet of forms. Dr. McCrea can be reached at 414-955-7300 or tbiresearch@mcw.edu.

THANK YOU FOR CONSIDERING PARTICIPATING IN THE ROLE OF REHABILITATION IN CONCUSSION MANAGEMENT

Brain Injury Research Program
8701 Watertown Plank Road
Milwaukee, Wisconsin, 53226
Direct: 414-955-7302 Email: mmccrea@mcw.edu

The Role of Rehabilitation in Concussion Management

Sport-related concussion is a significant public health problem in the United States and worldwide. An estimated 300,000 concussions occur in sports and recreation each year in the U.S. The current standard of care for sports-related concussion centers on cognitive and physical rest followed by gradual return to activity once the athlete no longer has symptoms. These progression protocols are not aimed at rehabilitating athletes following concussion, but rather serve as checkpoints for determining whether symptoms return with exertion. In response, **The Role of Rehabilitation in Concussion Management** is a research initiative intended to better understand what types of activities improve outcomes following a concussion.

If you decide to participate in this research project, the following procedures will take place:

1. You will undergo testing before the sports season to establish your baseline performance on various tests of thinking/memory, symptoms, balance and coordination.
   - The testing session will take place at your school and will last about 1.5 hours. You will be paid $20 for your time for completing the baseline testing.
2. If you sustain a sport-related concussion, you will undergo the same tests within 48 hours of your injury, when you are symptom free, and 1 month after your injury.
   - The testing sessions will take place at your school and will last about 1.5 hours. You will be paid $50 for your time for each testing session you complete.
3. You also may complete rehab exercises, supervised by a medical provider at your site, that work on your thinking, balance, vision, and general well-being four times per week until you have fully returned to play in your sport.
4. We may also ask you to track your activities (both physical and mental) and your symptoms each day until 7 days after you have fully returned to your sport. This may include wearing an activity tracking device (like a FITBIT).
5. After you return to play, we may also ask you some questions about your experience in the study and the care you received for your injury.

Points of Interest to Parents and Athletes:

1. These activities will take place with no cost to schools, athletic departments, athletes or families. This project is 100% supported by a research grant from the National Football League.
2. This project will be directed by Dr. Michael McCrea from Medical College of Wisconsin. The project has been approved by the Institutional Review Board (IRB) for the protection of human subjects at MCW.
3. Recommendations/decisions about return to play will not be made by the investigators, but left up to those usually responsible for making these decisions.

Parents and Athletes:

Thank you for considering participating in this project. If you have questions regarding this research project, feel free to contact Dr. McCrea:

Michael McCrea, Ph.D.
Department of Neurosurgery
Medical College of Wisconsin
Phone: 414-955-7300
Email: tbiresearch@mcw.edu

Medical College of Wisconsin and Froedtert Hospital
CONSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

Role of Rehabilitation in Concussion Management: A Randomized Controlled Trial

Multidimensional Active Rehabilitation Arm

Michael McCrea, PhD, ABPP-CN
Department of Neurosurgery
414-955-7300
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, and possible risks and benefits to you. If there is anything you do not understand, please ask questions. Then you can decide if you want to join this study or not.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

You are invited to participate in this research study because you participate in a contact sport at a high school in Southeastern Wisconsin.

A total of about 6,600 people are expected to participate in this study world-wide, including about 3,000 at the Medical College of Wisconsin.

The Director of the study is Dr. Michael McCrea in the Department of Neurosurgery. A study team works with Dr. McCrea. You can ask who these people are.
The National Football League is funding the study.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to understand what types of activities improve outcomes following a concussion.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Your school has been randomly selected to be part of the multidimensional active rehabilitation group. As part of this group you may complete the following:

- Pre-season baseline testing which will assess your processing speed, attention, learning, memory, immediate and delayed recall, concentration, and coordination, as well as include self-report demographics, medical history, symptoms, and quality of life of the participant. This baseline visit will last approximately 1 hour and 30 minutes.
- If during the study you become injured and are assessed by your athletic training staff to have a concussion, you may complete the post-injury protocol. This protocol includes the same baseline measures (excluding medical history) along with a more detailed demographic history and a timed gait/memory task at three predetermined time points. These three time points will be 24-48 hours post-concussion, when you no longer are experiencing symptoms, and 1 month after your concussion date. Each visit will last approximately 1 hour and 30 minutes and will take place in your normal athletic training or clinical environment of your school.
- Within the immediate 24-48 hours after your injury, you may also be asked to track your activities (both physical and cognitive), along with your symptoms each day until 7 days after you have fully returned to participation in your sport. This may include wearing an activity tracking device (like a FITBIT).The study team member at your school will be tracking your care over your recovery period.
- During the intervention, you may complete various rehabilitation exercises specifically set in place for your sport, all supervised by the athletic training staff at your school. These exercises will work on your thinking, balance, vision, and general well-being. This will be done 4 times per week until you have fully returned to play in your sport.
- Once you are no longer experiencing symptoms, you may continue to be progressed through the graded exertion protocol, while continuing to do your multidimensional exercises. This will be supervised by the athletic training staff at your school until you are fully cleared to return to play.
- Following your return to play, you may also be asked to complete some questions about your experience in the study and the care you received.

B2. HOW LONG WILL I BE IN THE STUDY?

All participants in this study will complete the baseline assessment, which will last approximately 1 hour and 30 minutes. You will be eligible to complete the post injury protocol until you stop participation in sports at your school.

Should you become concussed during the course of your season, you will be asked to complete the post-injury assessments and the active rehabilitation protocol for this study. The post injury assessments and active rehabilitation protocol will be conducted until 1 month following the date of your concussion. After one month post-injury, your participation in the study will end.

B3. CAN I STOP BEING IN THE STUDY?

You may stop participation at any time. If you decide to leave the study, please let the study team know.

The study investigator also has the right to stop your participation at any time without your consent. This could be because you have had an unexpected outcome, have failed to follow instructions, or because the entire study has been suspended. The study investigator will tell you if this happens.

C1. WHAT RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?

We observe everyone in the study for unexpected problems or events. **You need to tell the study doctor or a member of the study team immediately if you experience any problems.**

Your risk of experiencing discomfort or issues as a result of the interventions involved in this study is minimal.

- **Questionnaires/Testing:** You may feel that some of the questions we ask are stressful, upsetting, or cause you to feel discomfort. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset, please let a study member know.
- **Intervention:** When participating in the multidimensional active rehabilitation protocol of this study, you may experience increases in symptoms or other unknown discomforts. You should report these to the researchers and/or athletic training staff at your school. These individuals will decide if you should stop the post-injury activities during an assessment or exercise session. In addition, should you feel a need to stop, you may do so at any time. The research team as well as the athletic training staff at your school will help you get follow-up care if needed. There may be uncommon or previously unknown risks. You should report any problems to the research team.

Another risk may be loss of confidentiality. Every effort will be made to keep your study records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your study information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

C2. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study may or may not help you, but we hope the information from this study will help us develop a better treatment for concussion. If you become concussed during the course of the study, you may benefit from the post-injury intervention in terms of recovery from your injury.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?

There are no costs to you for any of the visits or services you receive in this study.

D2. WILL I BE PAID FOR BEING IN THE STUDY?

You will be paid $20 for completing the baseline testing procedures and an additional $150 should you suffer a concussion and complete *all* post-injury assessments. Each post-injury visit you complete you will receive $50.

In order to pay you, we will need your social security number. Any payment may be reportable as income on your taxes.

D3. WHAT OTHER CHOICES DO I HAVE?

You do not have to join this study. You are free to say yes or no. Whether or not you join this study, your usual medical services will not change.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?

If we learn any important or new information about the post-injury intervention that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to continue participation in the study.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE STUDY?

If you have been following directions, the injury is directly related to the research, and not the result of an underlying condition, then MCW will compensate you for the injury.

If you think you have been injured because of this study, let the study members know right away by calling 414-955-7300.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have more questions about this study at any time, you can call Dr. McCrea at 414-955-7300.

If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input you can call the Medical College of Wisconsin/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?

To be in this research study, the study team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, as described below. We will only collect and use information needed for the study.

The health information we will collect and use for this study is:
Health information collected during this study, such as questionnaires and assessments.
Health information collected by the medical staff at your school regarding your injury and treatment.

E2. Who will see the health information collected for this study?
The only people allowed to handle your health information are those on the study team at MCW/Froedtert Hospital, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed. The study team may share your information with people who are not part of the study team because they planned, pay for, or work with us on this study. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this study, we plan to share information with those doctors, researchers or government representatives working with us on this study at the institutions or companies listed here:

University of North Carolina, Chapel Hill, NC
National Football League, New York, NY

E3. What are the risks of sharing this health information?
One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

E4. How long will you keep the health information for this study?
If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?
If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Michael McCrea at 8701 Watertown Plank Road, Milwaukee, WI 53226. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

CONSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Consent of Adult Subject (18 years or older)		
Subject's Name ***please print***	**Subject's Signature**	**Date**

Assent of Minor Subject (younger than 18)		
Name of Minor ***please print***	**Signature of Minor**	**Date**
Consent of Parent/Guardian of Minor Subject		
Name of Parent/Guardian ***please print***	**Signature of Parent/Guardian**	**Date**